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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/873,601	06/12/1997	GARRY P. NOLAN	A-63915/DJB/	2070

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EXAMINER
FRIEND, TOMAS H F

ART UNIT	PAPER NUMBER
1639	35

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/873,601	Applicant(s) NOLAN ET AL.	
	Examiner Tomas Friend	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-80* is/are rejected.

7)☒ Claim(s) *58* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

Change of Art Unit Designation

Please note: The Art Unit location of this application in the PTO has changed from Art Unit 1627 to Art Unit 1639. To aid in matching papers to this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection (Paper No. 33). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 December 2002 has been entered.

The amendment received 26 December 2002 (Paper No. 34) has been entered.

Status of the Claims

Claims 58-80 are pending in the present application and are examined on their merits.

Withdrawn Rejections

1. All outstanding rejections of claims 58-80 made under 35 U.S.C. 112, second paragraph are withdrawn.

2. The rejection of claims 58, 59-62, 64-66, 68, 69, 72, 77, and 78 under 35 U.S.C. 102(e) as being anticipated by Khosla et al. U.S. Patent No. 5,672,491 is withdrawn in response to applicants' amendment.

Objections to the Claims

3. Claim 58 is objected to because it appears to be missing the word "*an*" between "*comprises*" and "*exogenous*" in method step (b).

Maintained Rejections

The statutory basis for each of the following rejections may be found in a prior office action.

Maintained Rejections – 35 U.S.C. 101

4. Claims 58-80 remain rejected under 35 U.S.C. 101 for reasons made of record in Paper Nos. 28 and 31.

Applicants argue that pages 42 (relating to tumors), page 50 (relating to HIV), page 51 (related to antibiotic toxicity) assert specific and substantial utilities for the claimed invention.

Applicants' argument has been fully considered but it is not persuasive. Applicants disclose that it would be desirable to use the claimed method to find bioactive compounds capable of [1] blocking cytokine or growth factor stimulation of tumors, [2] blocking CCR-5/HIV interactions, and [3] protecting organs from antibiotic or other drug toxicities. Applicants do NOT provide any specific link between a general method of screening a plurality of cells for an altered phenotype (or any embodiment thereof) and ANY of the unspecified desired compounds. Rather, applicants provide an invitation to experiment to determine which combinations of scaffolds, enzymes, and exogenous binding sites might be used in some combination to find some compound with one of any number of possible utilities. There does not appear to be a correlation between the concept represented by the claimed method and any specific and substantial utility.

Maintained Rejections – 35 U.S.C. 112, first paragraph

5. Claims 58-80 remain rejected under 35 U.S.C. 112, first paragraph, (Written Description) for reasons made of record in Paper Nos. 28 and 31.

Applicants argue that the description need only describe in detail what is new or not conventional and that, if a skilled artisan would have understood that the inventor was in possession of the claimed invention at the time of filing, the adequate description requirement is met. Applicants assert that protein-protein and protein-nucleic acid interaction domains were known in the art at the time of filing. Applicants assert that chimeric proteins containing binding sequences were in routine use and that recombinant enzymes and a variety of screening assays are described in the specification. Applicants indicate that by describing each of these individual components of the method, the written description requirement has been met.

Applicants' arguments have been fully considered but they are not persuasive.

Applicants' claims are drawn to a method of screening that requires the use of several components. Applicants were not in possession of full scope of the presently claimed method at the time of filing because applicants were neither in possession of the full scope of the components required nor of performing the method according to the claims using the required components to screen for a cell with an altered phenotype.

A library of nucleic acids encoding a library of exogenous scaffolds encompasses any combination of two or more nucleic acids that "encodes" any DNA, RNA, or (poly)peptide that can bind to any binding sequence that can be attached to at least two enzymes expressed in the same cells as the library members. Consequently, the members of the nucleic acid library must have a function (binding to an exogenous binding sequence). The binding sequences and scaffolds may comprise almost any nucleic acid or peptide sequence of any length with innumerable potential peptide-peptide and peptide-nucleic acid combinations. The disclosure does not indicate that applicants were in possession of representative examples of exogenous scaffolds that are representative of the claimed generic and used in the claimed method.

Enzymes comprising at least one exogenous binding sequence encompasses all enzymes including membrane-associated, transmembrane, cytosolic, extracellular, and lysozomal enzymes, as well as different classes of enzymes that catalyze chemically diverse reactions such

as electron transport, isomerizations, ATP synthesis, hydrolysis of peptide and phosphodiester bonds, and carbon fixation, for example. The binding sequences to which these enzymes are fused may or may not be any number of amino acid sequences that may bind to any number of binding sites within any nucleic acid or protein scaffold. The disclosure does not indicate that applicants were in possession of representative examples of enzymes with exogenous binding sequences that are representative of the claimed generic and used in the claimed method.

With regard to adequate written description of the claimed method, if a skilled artisan would have understood that the inventors were in possession of the claimed invention at the time of filing, the adequate description requirement is met. A skilled artisan would not understand the inventors to have been in possession of the claimed method at the time of filing. Applicants, have not described any correlations between enzymes, scaffold, binding sequences, and cells used, and the altered phenotype to be screened for.

6. Claims 58-80 remain rejected under 35 U.S.C. 112, first paragraph for reasons made of record in Paper Nos. 28 and 31.

The rejection made and maintained in Paper Nos. 28 and 31 are both based upon the rejection of the claims under 35 U.S.C. 101 and that one skilled in the art would not know how to use the claimed invention. The examiner regrets any confusion that may have been caused by inclusion of "(enablement)" or the answers to applicants' arguments in the maintained rejection.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend** at telephone number **(703) 308-4548**. The examiner's works on an increased flex-time schedule. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
21 March 2003

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600